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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,251	02/03/2004	Jack Millay	82378	2586
7590	02/23/2006			EXAMINER
Neal L. Slifkin 99 Garnsey Road Pittsford, NY 14534				TOTH, KAREN E
			ART UNIT	PAPER NUMBER
			3736	
				DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,251	MILLAY ET AL.	
	Examiner	Art Unit	
	Karen Toth	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 3 February 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-13 and 15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 14 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/4/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species:

Species I, drawn to Figure 4.

Species II, drawn to Figure 11.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 15 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. During a telephone conversation with Robert Brown on January 27, 2006 a provisional election was made with traverse to prosecute the invention of species I, claims 1-13 and 15. Affirmation of this election must be made by applicant in replying to this Office action. Claim 14 is withdrawn from further

consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

- (1) 22' as an element in Figure 7 (page 11)
- (2) 24' as an element in Figure 6 (page 11)

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be limited to a single paragraph within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1, 2, 6, 8-10, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroshaki'182 (US Patent 5660182) in view of Aronson'937 (US Patent 3906937).

7. Regarding Claim 1, Kuroshaki'182 teaches an inflatable cuff for use in inferential blood pressure measurement. Said cuff comprises an elongate outer layer (element 16) and an elongate inner layer (element 18) with an inflatable, elongate bladder (element 40) disposed therebetween. The bladder of Kuroshaki'182 is attached to the inner and outer layers of the cuff at both elongate ends (elements 30 and 34) and along one lateral edge (element 28).

Aronson'937 teaches an inflatable cuff for use in inferential blood pressure measurement wherein an inflatable bladder (element 20) is disposed within a hollow portion (element 12) of a cuff (element 10). Said bladder is constrained only on the elongate ends (elements 43 and 45) to prevent longitudinal movement (column 6, lines 51-55), and is free to expand across the width of the cuff to allow various amounts of contact for differing arm sizes.

It would have been obvious to one skilled in the art at the time the invention was made to have constructed the blood pressure cuff of Kuroshaki'182 with the improvements of Aronson'937, meaning attaching the bladder within the cuff only at the elongate ends, to accommodate various arm sizes.

8. Regarding Claim 2, Aronson'937 and Kuroshaki'182 teach all the elements of the current invention as discussed in paragraph 6 except for connecting the elongate ends to form a tubular shape with inner and outer surfaces.

Kuroshaki'182 further teaches forming a tubular shape from the cuff (element 10) by joining the opposite end portions of the cuff (column 10, lines 48-

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57) for the purpose of attaching the cuff to an extremity to measure blood pressure. The resulting tubular cuff (shown in Figure 5) has an outer surface (element 15) defined by the outer member (element 16) and an inner surface (element 17) defined by the inner member (element 18) (column 8, lines 43-45).

9. Regarding Claim 6, Aronson'937 and Kuroshaki'182 teach all the elements of the current invention as discussed in paragraph 6 except for the stiff intermediate layer disposed between the bladder and the outer layer of the cuff.

Aronson further teaches a resilient spring clip (element 34) located within the cuff between the bladder (element 20) and the outer layer (element 16) (column 5, lines 41-47). Said spring clip is included for the purpose of providing shape to the bladder (column 5, lines 48-49).

It would have been obvious to one skilled in the art at the time the invention was made to have constructed the blood pressure cuff of Kuroshaki'182 with the improvements of Aronson'937 as in paragraph 6, and further included a spring clip between the bladder and the outer layer of the cuff to provide shape to the bladder.

10. Regarding Claim 8, Aronson'937 and Kuroshaki'182 teach all the elements of the current invention as discussed in paragraph 6 except for composing the outer layer material from the group of nylon shell and rollable plastic sheeting.

Aronson'937 further teaches that the cuff cover (element 10) may be formed of material such as plastic, or any other non-elastic and non-stretchable

material (column 5, lines 21-24) to ensure that, when inflated, the bladder exerts enough pressure to occlude the artery in question.

It would have been obvious to one skilled in the art at the time the invention was made to have made the cuff of Kuroshaki'182 in view of Aronson'937 as discussed in paragraph 6, and further composed the outer layer of non-elastic material such as plastic to ensure that, when inflated, the bladder exerts the desired amount of pressure upon an artery.

11. Regarding Claim 9, Aronson'937 and Kuroshaki'182 teach all the elements of the current invention as discussed in paragraph 6 except for means for connection of the bladder to a controllable source of pressurized air.

Kuroshaki'182 further teaches a flexible tube (element 14) connected to the inflatable bladder (element 40) for the purpose of supplying air for inflation (column 9, lines 11-15).

12. Regarding Claim 10, Aronson'937 and Kuroshaki'182 teach all the elements of the current invention as discussed in paragraph 10 except for connecting said blood pressure cuff to an automated blood pressure machine.

Kuroshaki'182 further teaches that said cuff may be connected to an automatic blood pressure measuring device via an air pipe (element 14) (column 8, lines 37-43, and Figures 15 and 21).

13. Regarding Claim 12, Aronson'937 and Kuroshaki'182 teach all the elements of the current invention as discussed in paragraph 7 except for the cuff being suitable for stand-alone use.

Aronson'937 further teaches that said cuff is designed to be wrapped around an extremity and inflated by means such as a hand-squeezable pressure bulb (column 5, lines 3-8).

It would have been obvious to one skilled in the art at the time of the invention to have constructed the blood pressure cuff of Kuroshaki'182 with the improvements of Aronson'937 as in paragraph 7, and further employed said cuff by wrapping it around an extremity and inflating it by means such as a hand-squeezable pressure bulb.

14. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroshaki'182 in view of Aronson'937 as applied to claim 1 above, and further in view of Just'992 (US Patent 6988992).

Regarding Claim 3, Kuroshaki'182 and Aronson'937 teach all the elements of the current invention as discussed in paragraph 6 except for the inner layer of the cuff being formed from elastic material and the outer layer of the cuff being formed from inelastic material.

Just'992 teaches an inflatable blood pressure cuff (element 25) wherein the inner surface (element 25i) is composed of an elastomeric material (column 5, lines 56-66), and the outer surface (element 25o) is composed of material such as hook and loop fasteners (column 6, lines 4-8). This embodiment of the cuff provides elasticity and promotes patient comfort on the interior surface while retaining the external structure.

It would have been obvious to one skilled in the art at the time the invention was made to have composed the cuff of Kuroshaki'182 in view of

Aronson'937 as in paragraph 6, and further included the improvements of Just'992, meaning forming the inner surface of an elastic material and the outer surface of an inelastic material for the purpose of comfort.

Regarding Claim 4, Just'992 further teaches that the elastomeric material used to form the inner surface of the cuff (element 25i) should also be impermeable, meaning resistant to absorption to biofluids and easily cleaned or sanitized between uses for the purpose of promoting hygiene between patients (column 5, lines 56-66, and column 6, lines 1-3).

It would have been obvious to one skilled in the art at the time the invention was made³ to have composed the cuff of Kuroshaki'182 in view of Aronson'937 as in paragraph 6, and further included the improvements of Just'992, meaning forming the inner surface of an impermeable and resistant elastic material and the outer surface of an inelastic material for the purposes of comfort and hygiene.

15. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroshaki'182 in view of Aronson'937 as applied to claim 1 above, and further in view of Peters'734 (US Patent 4007734).

Kuroshaki'182 and Aronson'937 teach all the elements of the current invention as discussed in paragraph 6 except for the bladder additionally being attached to the outer layer of the cuff between the elongate ends.

Peters'734 teaches an inflatable blood pressure cuff (element 11) with a bladder (element 17) disposed between an inner (element 16) and outer surface (element 14). Said bladder is connected to the outer surface of the cuff by a set

of pressure switches (elements 23 and 24) for the purpose of signaling when the bladder is exerting predetermined pressures.

It would have been obvious to one skilled in the art at the time the invention was made to have constructed the blood pressure cuff of Kuroshaki'182 in view of Aronson'937 as in paragraph 6, and further added the pressure signaling switches of Peters'734, thereby connecting the bladder to the outer surface of the cuff.

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroshaki'182 in view of Aronson'937 as applied to claim 6 above, and further in view of Nishibayashi'356 (US Patent 6969356).

Kuroshaki'182 and Aronson'937 teach all the elements of the current invention as discussed in paragraph 7, except for the stiff intermediate layer being formed from rollable plastic sheeting.

Nishibayashi'356 teaches a blood pressure cuff (element 10) which has a cavity (element 36) which houses an inflatable bag (element 26) and a shield plate (element 38) located on the outer side of said bag. Said shield plate is formed of high density polyethylene (column 4, lines 26-28) and included for the purpose of structural support.

It would have been obvious to one skilled in the art at the time the invention was made to have composed the cuff of Kuroshaki'182 in view of Aronson as discussed in paragraph 7, and further composed the stiff intermediate layer of high density polyethylene as in Nishibayashi'356.

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17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroshaki'182 in view of Aronson'937 as applied to claim 2 above, and further in view of Lichowsky'353 (US Patent 3905353).

Aronson'937 and Kuroshaki'182 teach all the elements of the current invention as discussed in paragraph 7 except for incorporating said cuff into an automated blood pressure measurement machine.

Lichowsky'353 teaches an automated blood pressure measurement machine which includes an inflatable cuff (element 13) that is used to occlude the artery of the subject to enable pressure measurement.

It would have been obvious to one skilled in the art at the time the invention was made to have used the cuff of Kuroshaki'182 in view of Aronson'937 as discussed in paragraph 7, and used that cuff as part of the automated blood pressure measurement machine of Lichowsky'353 for the purpose of occluding the subject's artery during blood pressure measurement.

18. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroshaki'182 in view of Aronson'937 as applied to claim 2 above, and further in view of Sokol'844 (US Patent 3812844).

Aronson'937 and Kuroshaki'182 teach all the elements of the current invention as discussed in paragraph 7 except for said cuff being suitable for use on subjects having arm circumferences between about 18 and 50 cm.

Sokol'844 teaches an apparatus for measuring blood pressure that includes a bandage section which is pressurized with air (column 3, line 67 to column 4, line 1). The apparatus of Sokol'844 is constructed with adjustment

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rods (element 2) so as to be adaptable for use over limbs of varying diameters, between approximately 15 and 50 cm (column 4, lines 6-10).

It would have been obvious to one skilled in the art at the time the invention was made to have included the adjustment rods of Sokol'844 when constructing the cuff of Kuroshaki'182 in view of Aronson'937 as discussed in paragraph 7 for the same purpose, meaning ability to use the cuff on a wide variety of extremity diameters.

19. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroshaki'182 in view of Aronson'937 as applied to claim 1 above, and further in view of Ogura'869 (US Patent 5680869).

Aronson'937 and Kuroshaki'182 teach all the elements of the current invention as discussed in paragraph 1 except for an automated blood pressure measurement machine comprising a cylindrical housing for receiving an inflatable cuff.

Ogura'869 teaches an automated blood pressure measuring apparatus that includes an inflatable cuff (element 18) located in a cylindrical housing (element 16). Said inflatable cuff is used to apply pressure to the extremity of the subject for the purpose of measuring blood pressure (Figure 1).

It would have been obvious to one skilled in the art at the time the invention was made to have used the cuff of Aronson'937 in view of Kuroshaki'182 as discussed in paragraph 6 as the inflatable cuff portion of the automated blood pressure measuring apparatus of Ogura'869 to be used for apply pressure to the extremity of a subject to measure blood pressure.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5069219 to Knoblich discloses a blood pressure cuff of flexible, non-resilient, air-impermeable material.

US Patent 6551249 to Ashida et al. discloses a blood pressure cuff with an air bag arranged within an outer bag.

US Patent 4920971 to Blessinger discloses a blood pressure cuff with an internal surface of elastic nylon and an external surface of a hard cylindrical tube.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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ROBERT L. NASSER
PRIMARY EXAMINER

